

March 31, 2006

Donald Romano, Director
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Center for Medicare Management
Center for Medicare and Medicaid Services
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Via email: Donald.Romano@cms.hhs.gov

RE: New Physician Self-Referral Specialty Hospital Strategic and Implementing Plan – Methodology

Dear Mr. Romano:

On behalf of the American Physical Therapy Association (APTA), I would like to take this opportunity to offer comments to the Center for Medicare & Medicaid Service (CMS) as the agency moves forward to develop “a strategic and implementing plan” concerning physician investments in a specialty hospital and enforcement policies as mandated by the Deficit Reduction Act of 2005 (DRA). The APTA is a professional organization representing the interests of over 67,000 physical therapists, physical therapist assistants, and students of physical therapy. We ask that CMS consider the following recommendations as it analyzes existing data, formulates a strategic plan, and develops implementation procedures.

Conduct a Careful Analysis of Existing Resources

We understand the huge undertaking that has been put before CMS, and we are sensitive to the amount of time, effort, and resources that it will take to carry out such a mandate. Physician investment interest in specialty hospitals should be carefully monitored, analyzed and regulated, accordingly, due to the huge potential for fraud and abuse (i.e.

overutilization resulting from physician self-referral). Although we understand the agency's desire to comply with the initial six month time-frame as set forth by Congress, we urge CMS to take careful consideration and thorough inventory of all existing data in this subject area in order to create a strategic plan that is comprehensive and in the best interest of patients.

Coordination with the Office of the Inspector General

During the Special Open Door Forum held on March 8th, CMS stated that it planned to review information previously acquired through the Stark II rule reporting requirements and the Stark advisory opinion process, as well as, work with the Office of the Inspector General (OIG) to address uncovered violations of the Anti-kickback Statute. Although we think that these actions are a step in the right direction, we believe that further measures should be taken.

To determine the status of a physician's investment interest in a specialty hospital, it would be beneficial for CMS to review the OIG's criteria in the investment interest safe harbors under the Anti-kickback Statute. Generally, these investment interest safe harbors rely heavily on statutory definitions established by the Stark law and provide a framework of standards to consider when evaluating the legality of physician investment's in medical facilities. The safe harbor provisions consider the referral power of the investors, proportionality of dividends to investors, and the correlation between gross revenues and referrals generated by investors. We believe that these safe harbors provide guiding principles that will aid CMS in responding to investment interest inquiries as posed by the DRA.

The final strategic and implementing plan should involve implications and penalties under the Stark and Anti-kickback Statute, as well as, other existing fraud and abuse laws. Therefore, we believe that it is imperative that CMS not only refer to available OIG guidance, but the agency should make every effort from the initial development to implementation of the DRA mandates to coordinate with the OIG to ensure continuity with existing fraud and abuse statutes and proper enforcement.

Consideration of Physician Ownership of Physical Therapy Services

APTA understands the current mandates put before the agency and appreciates the federal government's acknowledgement of physician investment interest in specialty hospitals, but we would also like to highlight another physician ownership issue that CMS and the federal government need to address.

Physician ownership/interest in physical therapy, other specialty services and medical equipment is becoming a growing problem and often leads to overutilization and a

decline in quality health care. This has been evidenced in OIG studies¹ and reports published by the Medicare Payment Advisory Committee (MedPAC)². Of particular concern to the profession of physical therapy are the increasing instances of physical therapy referral for profit models appearing across the country. Physical therapy referral for profit arrangements are financial relationships in which a physician refers patients for physical therapy treatment and gains financially from the referral.

The APTA strongly supports the ban on physician self-referral. We oppose the underutilization and overutilization of services for personal or institutional gain, or participation that is any way linked to the provision of services for the financial gain of the referral source. Situations, in which physicians receive compensation as a result of referring for, prescribing, or recommending physical therapy services, create serious potential for abuse. APTA has seen a number of advertisements urging physicians to add a physical therapy clinic to their practice to make huge profits.

The Effects of Physical Therapy Referral for Profit Arrangements on the Healthcare System

First, a potential conflict of interest arises, in which the best interest of the patient may be compromised for financial gain when physicians own physical therapy practices. For example, the physician may refer the patient for physical therapy services that are not needed or unnecessarily lengthen the period of treatment.

Secondly, there is the issue of self-referral to physical therapy services offered within the physician's office suite. This practice, essentially, limits the patient's right to choose his or her physical therapist. The patient may be unaware of this loss in choice because there are no other options offered. Observation of the fiduciary responsibility between the physician and patient is vital to preserving patient choice.

Lastly, health policy researchers have provided data demonstrating specific harms from conflict of interest in physical therapy referrals to physician owned services. These studies indicate that physical therapy referral for profit arrangements have a significant adverse economic impact on patients and third-party payers. In a study examining the costs and rates of use in California Workers' Compensation system³, it was reported that physical therapy was initiated 2.3 times more often by physicians in self-referral relationships than by those referring to independent practices. Another study documented higher utilization rates and higher costs associated with services provided in joint venture

¹ Office of the Inspector General, Department of Health and Human Services. 1994. *Physical Therapy in Physician's Offices*, no. OEI-02-90-00590. Washington, DC: OIG. March.

² Medicare Payment Advisory Committee. 2004. *Report to Congress: Growth in the Volume of Physician Services*. Washington, DC: MedPAC.

³ Swedlow A, Johnson G, Smithline N, Milstein A. Increased costs and rates of use in the California workers' compensation system as a result of self-referral by physicians. *NEJM*. 1992;327:1502-1506.

clinics in the state of Florida. The study revealed greater utilization of physical therapy services by joint venture clinics, rendering on average about 50 percent more visits per year than their counterparts, who did not own physical therapy services.⁴

Therefore, APTA urges CMS to create and implement regulatory measures to discourage physician self-referral of physical therapy services. We believe that this can be achieved by strengthening the Physician Self-Referral (STARK) laws, specifically, by prohibiting such arrangements, currently permissible, under the “in-office ancillary” exception.

The purpose of the Stark II law was to discourage financial incentives from influencing the delivery of care. APTA believes that these exceptions, as implemented, are not effective in restraining physicians’ financial interests from influencing care. Instead, they have become opportunities to increase the volume of services provided, which may be inappropriate. Physician self-referral creates a potential conflict of interest and must be avoided to protect patients and the overall healthcare system.

Conclusion

We thank you for the opportunity to provide comments on the new physician self-referral specialty hospital strategic and implementing plan and methodology as mandated by the DRA. We would welcome the opportunity to further discuss the issue of physician owned physical therapy services and to provide additional data and analysis. Please feel free to contact Roshunda Drummond-Dye, Associate Director of Regulatory Affairs at (703) 706-8547 or at roshundadrummond-dye@apta.org.

Sincerely,

G. David Mason
Vice President, Government Affairs

⁴ Mitchell JM, Scott E. Physician ownership of physical therapy services. JAMA. 1992;268:2055-2059.